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| APPLICATION NO.     | FILING DATE   | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |  |
|---------------------|---------------|-----------------------|-------------------------|------------------|--|
| 10/055,290          | 01/23/2002    | Benjamin Curtis Stone | 7533                    |                  |  |
| 7590 10/08/2003     |               |                       | EXAMINER                |                  |  |
| Benjamin Curt       | tis Stone     | WINAKUR, ERIC FRANK   |                         |                  |  |
|                     | APITAL STREET | ART UNIT              | PAPER NUMBER            |                  |  |
| Iowa City, IA 52240 |               |                       | 3736                    | 11               |  |
|                     |               |                       | DATE MAILED: 10/08/2003 | l /              |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

| ¥   |   |                      |                   |  |                             |  |  |  |
|---|---|----------------------|-------------------|--|-----------------------------|--|--|--|
| Office Action Summary   |   | Application N        | O                 | Applicant(s)                                 | $\mathcal{C}_{\mathcal{A}}$ |  |  |  |
|   |   | 10/055,290           |                   | STONE, BENJAMIN CURTIS                       |                             |  |  |  |
|   |   | Examin r             |                   | Art Unit                                     |                             |  |  |  |
|   |   | Eric F Winaku        |                   | 3736   | ld-s-s-                     |  |  |  |
| The MAILING DATE of this c mmunication appears on the cover sheet with the correspondence address Period for Reply  |   |                      |                   |  |                             |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |                      |                   |  |                             |  |  |  |
| 1) Responsive to communication(s) filed on  |   |                      |                   |  |                             |  |  |  |
| 2a)□  |   |                      |                   |  |                             |  |  |  |
| 3)  | Since this application is in condition for allowa   |                      |                   | osecution as to th                           | e merits is                 |  |  |  |
| closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. <b>Disposition of Claims</b>  |   |                      |                   |  |                             |  |  |  |
| 4) Claim(s) 1-20 is/are pending in the application.   |   |                      |                   |  |                             |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.  |   |                      |                   |  |                             |  |  |  |
| 5)⊠ Claim(s) <u>14,15,19 and 20</u> is/are allowed.   |   |                      |                   |  |                             |  |  |  |
| 6)⊠ Claim(s) <u>9-13 and 16-18</u> is/are rejected.   |   |                      |                   |  |                             |  |  |  |
| ·   | Claim(s) <u>1-8 and 12</u> is/are objected to.  |                      |                   |  |                             |  |  |  |
| •   | Claim(s) are subject to restriction and/o   | or election requi    | rement.           |  |                             |  |  |  |
| · · ·   | The specification is objected to by the Examine   | er                   |                   |  |                             |  |  |  |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  |   |                      |                   |  |                             |  |  |  |
| ,—  | Applicant may not request that any objection to th  |                      | <del>-</del>      |  |                             |  |  |  |
| 11)   | The proposed drawing correction filed on  | _ is: a)∏ appro      | oved b)⊡ disappro | ved by the Examin                            | er.                         |  |  |  |
| If approved, corrected drawings are required in reply to this Office action.  |   |                      |                   |  |                             |  |  |  |
| 12)☐ The oath or declaration is objected to by the Examiner.  |   |                      |                   |  |                             |  |  |  |
| Priority under 35 U.S.C. §§ 119 and 120   |   |                      |                   |  |                             |  |  |  |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).   |   |                      |                   |  |                             |  |  |  |
| a) All b) Some * c) None of:  |   |                      |                   |  |                             |  |  |  |
| 1. Certified copies of the priority documents have been received.   |   |                      |                   |  |                             |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No  |   |                      |                   |  |                             |  |  |  |
| <ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>   |   |                      |                   |  |                             |  |  |  |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  |   |                      |                   |  |                             |  |  |  |
| a) The translation of the foreign language provisional application has been received.  15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.   |   |                      |                   |  |                             |  |  |  |
| Attachment(s)   |   |                      |                   |  |                             |  |  |  |
| 2) Notic  | ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449) Paper No(s) | 4) [<br>5) [<br>6) [ |                   | (PTO-413) Paper No<br>Patent Application (PT |                             |  |  |  |

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#### **DETAILED ACTION**

#### Claim Objections

1. Claims 1 - 8 are objected to because of the following informalities: In claim 1, line 10, the phrase "can further be configured" should read "further configured" to positively claim the limitation; the claim should end with a period instead of a semicolon. Appropriate correction is required.

#### Claim Rejections - 35 USC § 112

- 2. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 3. Claims 9 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 9, lines 14 15, the phrase "said puncture site" lacks antecedent basis. It appears that the term "puncture" should be deleted from the phrase.

## Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 5. Claims 9, 13, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Golden. Golden, as shown in Figures 1 and 3, teaches a hypodermic device for use with multiple vacuum tubes and method of its use. The device includes a first portion

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for puncturing a patient's skin and a second portion having multiple positions for attaching the vacuum tubes. As such, although only one skin puncture is required, multiple samples can be taken without contamination between the samples. The collected samples are suitable for use in diagnostic tests.

## Claim Rejections - 35 USC § 103

- 6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 7. Claims 10, 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Golden as applied to claims 9 above. Golden teaches that vacuum tubes are used to obtain the samples, but does not particularly teach that the vacuum tubes contain liquid culture media or sodium polyanethole sulfonate. However, these are merely well known additives to include in blood collection tubes. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to implement Golden with collection tubes that contained liquid culture media or sodium polyanethole sulfonate since it has generally been held to be within the skill level of the art to include well known elements in an invention.
- 8. Claims 13, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Golden for the reasons given in paragraph 7 above.

#### Allowable Subject Matter

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- 9. The following is a statement of reasons for the indication of allowable subject matter: Vailancourt teaches a dual chamber syringe. Van Vlasselaer teaches another syringe structure. None of the prior art teaches or suggests a collection vessel including a hollow body, a plunger disposed within the hollow body, and a plunger lock coupled to the plunger, wherein the plunger lock is configured to selectively maintain the plunger at a second end of the hollow body when at least a portion of the hollow body is partially evacuated and is further configured to release the plunger. Further, the prior art does not teach or suggest a method of using such a device or a kit including such a collection vessel. The prior art does not teach a method that includes at least patially filling a first and second sterile evacuated specimen tube such that a second end of a fluid collection needle is not contaminated by the sterile seal of the first sterile evacuated specimen tube and transferring the second body fluid specimen to an evacuated culture vessel which is then used for a diagnostic test.
- 10. Claims 1 8 would be allowable if rewritten or amended to overcome objections set forth in this Office action.
- 11. Claims 12 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
- 12. Claims 14, 15, 19, and 20 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric F Winakur whose telephone number is 703/308-3940. The examiner can normally be reached on M-Th, 7:30-5; alternate Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 703/308-3130. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0858.

Eric F Winakur Primary Examiner Art Unit 3736

1 October 2003